Local clinical guidelines: description and evaluation of a participative method for their development and implementation

CWR Onion, CE Dutton, T Walley*, CJ Turnbull**, WT Dunne† and IE Buchan*


**Background.** National guidelines are rarely followed by immediate change in clinical behaviour. We present our experience of an active educational method for local development and implementation of a guideline.

**Objective.** To evaluate the effectiveness of a participative method for developing local clinical guidelines.

**Methods.** A trial in a district of the effect of guideline development incorporating active participation of intended recipients on subsequent relevant prescribing. It was carried out in Wirral Family Health Services Authority district (the Wirral peninsula) comprising 69 general practices covering a population of 345 763. An exemplar guideline on ‘hypertension in the elderly’ was developed by the method described. The principal recommended drug was bendrofluazide 2.5 mg once daily. The differences in prescribed daily doses (PDD) of bendrofluazide 2.5 mg tablets per quarter per 1000 prescribing units (age-weighted population) between the intervention district and England as a whole was measured.

**Results.** Comparison of the intervention district with England data demonstrates a median difference of 122.49 PDD before and 206.34 PDD after guideline production, this change is statistically highly significant (Mann-Whitney two-tailed \( P < 0.0001 \); 95% CL = 36.51–104.77). Grouped regression analysis shows no significant difference (0.89) in slope gradients before guideline production \( (P = 0.35, 95\% \text{ CL} = -3.97–5.76) \), but the difference in slope gradients after (12.95) is statistically highly significant \( (P < 0.0001; 95\% \text{ CL} = 8.17–17.73) \). The data suggests that the change in clinical behaviour persisted for at least two years.

**Conclusion.** Participation of intended recipient general practitioners and local specialists in the development of a guideline by an active educational method as described was followed by a favourable change in clinical behaviour which persisted for at least two years.

**Keywords.** Clinical guidelines, development, evaluation, implementation, participation.

**Introduction**

The application of scientific research into clinical practice is crucial if the credibility of the medical profession is to be maintained and its effectiveness optimized. Science-based medical practice is pursued through medical education and, increasingly, through the development and publication of clinical guidelines. Despite concerns expressed by some that guidelines infringe upon clinical liberty, most support their development. Significant reservations remain however, so a cautious and careful approach has been advocated. To be valid guidelines should arise from a systematic appraisal of current scientific evidence and
are more likely to be adopted if intended users are involved in either development or implementation. Some authors advocate developing national guidelines through rigorous and exacting analysis of all published evidence plus health economic research and surveys of doctor and patient preferences. Such guidelines can act as a useful basis for local educational initiatives.

The development of national guidelines by Royal Colleges and others offers economies of scale and instant credibility. Disappointingly, such guidelines are rarely followed by rapid changes in clinical behaviour. Implementing guidelines requires as much thought and effort as drawing them up, and is the least explored guideline issue. Guidelines arising solely from remote academics and senior members of the profession may appear difficult to apply in everyday practice and can quickly lose credibility. We present here our experience of an active educational method for local development and implementation of a guideline, potentially applicable to other clinical topics.

Method

In January 1992 a group of Wirral clinicians (the editorial board) devised a method for developing local clinical guidelines through active education (Figure 1). Hypertension in the elderly was selected as a topic to test the method because scientific evidence suggested that more active approaches to treatment are likely to reduce morbidity and mortality from stroke and coronary artery disease. Increased detection and treatment of hypertension in the elderly had been identified as an important public health objective, and the management of elderly hypertensives in general practice was highly variable. Copious published recommendations on treatment of elderly hypertensives, including local bulletins, appeared to have had limited effects on actual prescribing. It was hoped that a local guideline initiative would stimulate appropriate changes. The method adopted was evaluated and change within the district of an indicator of the advocated clinical approach was compared with data for all England.

An editorial board was chosen to ensure a wide representation of interested parties and to incorporate necessary general expertise. The intention was to commission clinicians well-versed on the issue to develop draft guidelines. The 'scientific and specialist' draft would be thrown open to criticism by as many of the potential recipients as possible. These criticisms, drawn from experience and knowledge, would be used to refine the draft. It was hoped that the result would be both scientifically valid and applicable in practice, everyone involved would gain some educational benefit, and that appropriate changes in clinical management would follow. It was also felt that the final product should be succinct if it was to be of use in busy surgeries and a target was set of a maximum of two sides of A4 for the final printed form. The method is consistent with the approach reported previously in Islington, but with more active participation of intended recipients.

Phase 1: commissioning of a draft guideline

An editorial board (Table 1) commissioned a working party to develop a draft guideline for the chosen topic. The board oversaw the process and took overall responsibility for the guideline content. The first topic (hypertension in the elderly) was chosen because of evidence of substantial sub-optimal and variable practice where improvements were likely to be observable.

Phase 2: completion of the draft guideline by the working party

The working party was intended to be small and to contain a balance of specialists and generalists, one of each for the initial guideline. The members were sent recent scientific information on the topic and were asked to consider the evidence prior to deriving the draft guidelines. Their remit was to develop a clear concise draft based upon their considered appraisal of current relevant published evidence and their own experience.

Phase 3: scrutiny of the draft by the editorial board

Upon receipt of the working party draft the editorial board met to make any necessary refinements before
TABLE 1 The members of the editorial board

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<th>Editorial board:</th>
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<tr>
<td>Consultant Clinical Pharmacologist</td>
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<td>FHSA Medical Adviser (chairman)</td>
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<td>FHSA Pharmaceutical Adviser</td>
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<td>GP Audit Facilitator</td>
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<td>GP Postgraduate Clinical Tutor</td>
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<td>Hospital Audit Committee representative</td>
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<td>Local Medical Committee representative</td>
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<td>Public Health Physician</td>
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wider distribution. These refinements were confined to format and writing style.

Phase 4: discussion meetings with local clinicians
The refined draft was sent to all consultant specialists and general practitioners in the district. The recipients were invited to comment by post or engagement in critical discussion at either of two specific postgraduate educational meetings. The objective was to ensure systematic scrutiny of the draft without imposition of one particular clinical view. The round-table meetings were conducted so as to ensure deep scrutiny of the content by the attendees and, in view of the large size of the groups (up to 35 doctors), required an experienced medical chairman.

Phase 5: incorporation of conclusions by the editorial board
All comments were recorded. Obvious improvements (such as logical errors) were incorporated in secondary draft guidelines by the editor. The secondary draft and other comments were considered by the editorial board for inclusion in the final document.

Phase 6: dissemination and promotion of the final guideline
The resulting final guideline (Figure 2) was distributed to every local general practitioner. One side of A4 comprised a clinical algorithm. The reverse side was filled with supporting information which specifically identified bendrofluazide 2.5 mg as the drug of first choice. Occasionally opportunities were taken during routine visits to practices by the authority's medical and pharmaceutical advisers to discuss the issue of guidelines in general, and of the hypertension in the elderly guidelines in particular. This reinforced the messages in the guideline and, for those who had not attended the meetings, it was another opportunity for discussion and followed the established model of practice visit.

Phase 7: audit and review of the guideline
The effect of the guideline on clinical practice was monitored by the editorial board, and its content was reviewed on an annual basis for consistency with recent published evidence.

Each phase was evaluated with regard to attendance and time involved. As a measure of the effectiveness of the "hypertension in the elderly guideline" the rate of prescribing of the principally recommended drug in the district was compared with England as a whole. The trends before and after within the district were also analysed. The principal drug, bendrofluazide in its 2.5 mg strength at one tablet per day, is specifically recommended for hypertension. It is also prescribed once daily as a maintenance dosage in mild oedema. As there were no local recommendations for its use in oedema any change in its prescribing rate could act as a useful indicator of change in the local management of hypertension. A robust non-parametric test was applied to determine any change in prescribing relative to the national (England) picture, and regression analysis was used to investigate the persistence of any new trend.

Prescribing data was obtained from the Prescription Pricing Authority PACT reports (Prescribing Activity and Cost). The Wirral data is one month behind the England data, but was treated as synchronous for the purpose of analysis.

Results
There was a mean attendance of 66% (6/9) at each editorial board meeting. The educational meetings were also well attended with a total of 65 local general practitioners (36%) taking part in the discussions. Only four doctors made comment by letter and two of them, including a cardiologist, subsequently attended the meetings. Standard postgraduate education evaluation forms were completed by the attendees and the responses were favourable; 71% felt that the meeting was useful. Their criticisms of the draft guideline resulted in important, but not substantial revision. For example, the section on non-drug treatment was expanded and monitoring criteria were clarified: the participants incorporated 'reduce salt intake' advice despite scientific controversy, and set themselves a six-monthly target for urea and electrolyte testing despite the practical difficulties entailed. The logistics of the project meant that six months elapsed before the finished product was apparent, although the actual time devoted to the work was 27 hours (Table 2). In annual reviews of the guideline by the editorial board in 1993 and 1994 the view was taken that revision was unnecessary as the guideline remained consistent with published recommendations.
Local clinical guideline initiative

**HYPERTENSION IN THE ELDERLY**

- **3 BP readings over 3 weeks**
  - **SBP > 160 or DBP > 100**
  - Investigate Urinatysis, U/E
  - **Non-Drug Treatment**:
    - Weight loss
    - Reduce Alcohol
    - No Smoking
    - Reduce Salt intake
    - Exercise
    - Relaxation

- **BP not Controlled**
  - SBP > 160 or DBP > 100
  - Add drug treatment
  - Monitor BP and U + E 6 monthly
  - Target BP SBP <160, DBP <90

- **BP Controlled**
  - SBP < 160 or DBP < 100
  - Monitor BP Monthly over 3 - 4 months
  - BP Controlled
    - SBP < 160 or DBP < 100
    - Life style advice only

**FIGURE 2** The final form of the local guideline on hypertension in the elderly. Supporting text filled the reverse side including the specific recommendation of bendrofluazide 2.5 mg as the drug of first choice. (With permission of the Postgraduate Medical Journal.)

**DRUG TREATMENT**
Prescribing rates were measured in prescribed daily doses (PDD) of bendrofluazide 2.5 mg per quarter (three monthly period) per 1000 prescribing units. The PDD was defined as one 2.5 mg tablet per day. The prescribing unit (PU) represents the number of people registered with NHS general practitioners, with a standard weighting of 3.0 for individuals over 65 years of age. This weighting compensates for the higher level of medicines use by the elderly and standardized the district and all England populations for comparison.

Data is available for nine quarters before the guideline was produced, and eight quarters after (Figure 3). The median differences between the intervention group and the England data were 122.49 PDD before the guideline, and 206.34 PDD after. The change is statistically highly significant (Mann-Whitney two-tailed test; \( P < 0.0001 \) with 95% CL of 36.51-104.77).

After linear regression the slopes were compared. There was no significant difference between the Wirral (22.21) and England (23.1) slope gradients before the intervention (difference = 0.89, \( P = 0.7, 95\% \) CL = -3.97-5.76). However, after the guideline the difference between Wirral (36.71) and England (23.76) slopes was statistically highly significant (difference = 12.95, \( P < 0.0001, 95\% \) CL = 8.17-17.73).

The results are consistent with a highly significant change in clinical behaviour which has persisted for at least two years, although it is reasonable to expect the effect to tail off at some point in the near future.

**Discussion**

Developing a clinical guideline is a major undertaking and requires enthusiastic effort on the part of already busy clinicians. Topics must therefore be carefully chosen with regard to where significant benefit is possible and where new evidence creates sufficient enthusiasm. Producing a guideline by the method...
described takes six months. Holding meetings over working lunches minimizes opportunity costs for contributors.

The guideline, although intended to cover most cases, allowed the tailoring of clinical management to the individual patient or circumstances to be taken into account, and necessarily reflected the local situation and preferences. This was made explicit throughout the process. Evidence from controlled scientific trials may not be entirely applicable in general medical practice; similarly, hospital experience may not apply in the community. Collective evaluation of the evidence was intended to ensure that the guideline was applicable in practice whilst retaining scientific validity.

The educational meetings added value to the project by stimulating interactive discussion of the issues. Results of a postal survey of general practitioners in the intervention district prior to the intervention had shown a substantial majority supported the development of clinical guidelines; 86% thought that the effect of guidelines on clinical practice was beneficial and 72% intended to make greater use of guidelines in the future. This was corroborated by the high turnout at the clinical discussion meetings. Over 40 suggestions for improvement of the draft arose from the practitioners at these meetings, of which a quarter were incorporated. Specialists and generalists gaining an understanding of each others' perspectives was a welcome secondary achievement of the project. Involvement of practitioners in guideline development is known to increase compliance. One might expect attendance rates to decline with time, and this is indeed our experience, but we have still been able to achieve around 20% involvement of local general practitioners with each of six subsequent guidelines.

Although our results are encouraging we are conscious that caution should always be observed when drawing conclusions about the whole from examination of a part. PACT data cannot be linked to diagnosis, which is a weakness. However, in its favour it is collected objectively and with a high degree of precision. Fortunately, bendrofluazide 2.5 mg tablets are relatively specific to hypertension and can act as an indicator of change for this particular topic. We are aware of no other local promotion of bendrofluazide 2.5 mg in hypertension at the time of the intervention. To address the limitations described, however, a more detailed controlled study of the method in the production of guidelines for the management of infections has been undertaken. This not only examines prescribing, but also investigation, referral and individual case management; and compares active participation in development with passive receipt of the guidelines.

Audits of subsequent guidelines in the district developed using the same method show similar magnitudes of change in relevant prescribing. The method has also been popular and effective in developing depression guidelines in another district.

Recent evidence suggests that published evidence and national guidelines have changed general practitioners' attitudes (if not perhaps behaviour) towards the management of hypertension in the elderly. This study demonstrates how local initiatives ensure that changed attitudes are followed by consistent behaviour. The value of deep scrutiny of issues is well established in medical education, and face to face meetings with visiting professionals have been shown to change prescribing behaviour. In local guideline implementation it may be necessary to allow intended recipients' opinion to take precedence over purely scientific recommendations in order to make guidelines applicable in practice and gain maximum educational value.

Conclusion

The method safeguarded the basic scientific validity of the clinical guidelines while still permitting clinicians to contribute their opinions freely. Specialists and generalists working together in guideline development was popular and harmonized approaches. Involvement of intended recipients in active critical scrutiny of the draft guideline was followed by appropriate and persistent change in clinical behaviour in the district. The educational and practical benefits derived from this method generated sufficient local enthusiasm for the development of several subsequent guidelines on various clinical topics.

Acknowledgements

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